

Exhibit H

Confidential - Subject to Stipulation and Order of Confidentiality

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2 :SUPERIOR COURT OF
:NEW JERSEY
3 IN RE: :LAW DIVISION -
PELVIC MESH/GYNECARE :ATLANTIC COUNTY
4 LITIGATION :
:MASTER CASE 6341-10
5 :
:CASE NO. 291 CT

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CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
7 CONFIDENTIALITY

8 - - -
9 May 18, 2012

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11 Transcript of the deposition of
12 SEAN M. O'BRYAN, called for Videotaped
13 Examination in the above-captioned matter, said
14 deposition taken pursuant to Superior Court Rules
15 of Practice and Procedure by and before Maryellen
16 Coughlin, a Certified Realtime Reporter,
17 Registered Professional Reporter, and Notary
18 Public for the Commonwealth of Massachusetts, at
19 the offices of Campbell Campbell Edwards &
20 Conroy, P.C., One Constitution Center, 3rd Floor,
21 Boston, Massachusetts, commencing at 10:05 a.m.

22 - - -
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1 warnings that a patient could be faced with that
2 are important for the patient.

3 Q. And to the extent you had input
4 into the Prolift® IFU drafting process, you
5 certainly wanted to make sure that any warnings
6 of any significant potential risks would be
7 explicitly communicated to the intended or
8 foreseeable users of the Prolift®, correct?

9 MS. KABBASH: Objection.

10 A. Sure. I rely on the medical team
11 to tell me what is significant and what is
12 important to convey into the instructions for
13 use, package insert.

14 Q. When you worked on that project, it
15 was your understanding from an FDA regulatory
16 perspective it would not be legitimate to not
17 include warnings of potentially significant
18 adverse events based on a decision that the
19 surgeons would figure that out on their own?

20 MS. KABBASH: Objection.

21 A. No, that's correct.

22 Q. Would you turn to Page 22, please.
23 It's Paragraph D, D.1.3. The question is asked,
24 "Do the results of the design validation
25 performed as a result of this change in materials

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1 A. Yes, yes.

2 Q. Do you know if those were done by
3 the TVM or the Prolift® procedure or by other
4 procedures?

5 A. I can't recall. I'm sorry.

6 Q. You were asked by counsel about
7 whether or not it was your responsibility to make
8 sure adverse events were properly communicated in
9 the IFU, and I think you said your responsibility
10 to make sure that once medical affairs decided
11 that those adverse events belonged, were
12 significant enough that they needed to be
13 communicated because they were risks associated
14 with the Prolift®, you want to make sure that it
15 would not be presented in a confusing way,
16 correct?

17 A. Yes.

18 Q. And part of that would be that if
19 such a risk was known and was going -- rephrase.

20 And part of that would be that
21 if -- rephrase.

22 This is the last question of the
23 day. And part of that review that you're talking
24 about would include making sure that, to the
25 extent a risk did need to be included in the IFU,

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1 because, as you said, if it's known by medical
2 affairs to be a risk connected to the Prolift® it
3 should be in there, you don't want it to be
4 presented in a confusing way, and you want it to
5 be explicitly and clearly set forth, correct?

6 MS. KABBASH: Objection.

7 A. That's a fair assessment, yeah.

8 MR. SLATER: No other questions.

9 MS. KABBASH: I think we're done.

10 THE VIDEOGRAPHER: Person on the
11 phone any questions?

12 This concludes the May 18th, 2012,
13 deposition of Sean M. O'Bryan. The number of
14 tapes used today was 3. We are off the record at
15 4:59 p.m.

16 (Deposition suspended/concluded
17 at 4:59 p.m.)

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